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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,571	03/03/2004	Neil T Dear	ABB10010P0630US	9704
32116 7590 11/14/2007 WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661			EXAMINER SWOPE, SHERIDAN	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 11/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/009,571

Applicant(s)

DEAR ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response on August 30, 2007, to the Final Rejection of this case mailed June 1, 2007, is acknowledged. It is acknowledged that no claims have been cancelled, amended, or added. Claims 1-6 are pending. Claim 6 was previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-5 are hereby reconsidered.

Drawings

Objection to Figure 1 for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:) is maintained; corrections have not been made.

Specification-Objections

Objection to the specification for improper formatting is maintained; corrections have not been made.

Objection to the specification for containing hyperlinks is maintained; corrections have not been made.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Utility

Rejection of Claims 1-5 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility, for the reasons set forth in the prior actions, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

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(A) The use of the claimed polypeptide as bait for identifying inhibitors and subsequent use of said inhibitors for treatment of, for example male infertility, is a specific, substantial, and credible utility.

(B) CAPN11 is most strongly expressed in testis. Since calpains in other tissues are involved in certain processes, such as germ cell apoptosis and regulation of transcription factors, suggestion that CAPN11 may be involved in similar processes in the testis is a reasonable and convincing theory.

(C) Ben-Aharon states that expression of CAPN11 during spermatogenesis and its localization in spermatozoa suggest that it is involved in regulating calcium-dependent signal transduction during meiosis and sperm function.

(D) The fact that substrates of CAPN11 are not known, does not negate the utility for the claimed invention.

(E) Methods for assaying CAPN11 activity are known in the art and inhibitors of SEQ ID NO: 2, identified using said methods, are useful for treatment of infertility.

(F) Other [families of] intracellular cysteine proteases, to which CAPN11 belongs, are related to male fertility (Honbou et al, 2003).

These arguments are not found to be persuasive for the following reasons.

(A) Reply: Applicants' CAPN11 polypeptide cannot be used for identifying inhibitors because an assay for measuring activity has not been provided i.e., substrates and assay conditions to be used. Moreover, even if the specification provided an inhibitor assay using an artificial substrate, which it does not, the specification fails to teach the skilled artisan how to use any inhibitor of CAPN11 activity. The specification fails to teach any specific diseases or

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disorders to be treated or diagnosed or any specific cellular or biochemical processes to be analyzed. Mere assertion that inhibitors of CAPN11 activity can be used to treat infertility does not provide a patentable utility for Applicants' protein.

(B) Reply: It is acknowledged that CAPN11 is most strongly expressed in testis and that some calpains in some tissues are involved in germ cell apoptosis and regulation of transcription factors. However, mere expression of CAPN11 in testis is not sufficient evidence to convince the skilled artisan that, more likely than not, CAPN11 is involved in germ cell apoptosis and/or regulation of transcription factors. In addition, even four years after Applicants' filing date, Branca et al, 2004 teach that the physiological function of calpains is still unclear and that essentially all cellular events (proliferation, cell cycle, differentiation, gene expression, cytoskeletal reorganization, motility, apoptosis) have been claimed to be mediated by calpains (pg 1098, para 1). Neither the specification nor the prior art provide evidence that the protein of SEQ ID NO: 2 mediates any one specific process encompassed by this broad laundry list of cellular events.

(C) Reply: This is the same argument Applicants put forth in their response of November 13, 2006. Applicants are directed to the Office's "Reply (D)" on page 4 of the Action mailed January 12, 2007.

(D) Reply: It is acknowledged that, the fact that substrates of CAPN11 are not known, would not negate the utility for the claimed invention, if other evidence were provided for a patentable utility. However, no evidence is provided by which the skilled artisan would believe that, more likely than not, the protein of SEQ ID NO: 2 has a specific, substantial, and creditable utility.

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(E) Reply: It is acknowledged that methods for assaying some calcium-dependent proteases are known in the art. However, as explained in the Actions of June 1, 2007, January 12, 2007, and August 8, 2006, methods for identifying inhibitors of the protein of SEQ ID NO: 2 are not enabled or described because an assay for measuring activity has not been provided i.e., substrates and assay conditions to be used. Moreover, the specification fails to teach the skilled artisan how to use any inhibitor of CAPN11 activity to treat or diagnose any specific diseases or disorders. Mere assertion that inhibitors of CAPN11 activity can be used to treat infertility does not provide a patentable utility for the protein of SEQ ID NO: 2.

(F) Reply: It is acknowledged that Honbou et al, 2003 teaches a multifunctional protein suggested to be involved in male fertility. However, the teachings of Honbou et al cannot be used as evidence to support Applicants' assertion that the protein of SEQ ID NO: 2 is involved in male fertility for the following reasons. (i) Honbou et al was published after Applicants' priority date of June 7, 2000; (ii) the protein of Honbou et al is a multifunctional protein involved, not just in male fertility, but also Parkinson's disease, the hydroperoxide response, and glutamine amidotransferase activity; and (iii) the protein of Honbou et al, as originally disclosed by Nagakubo et al, 1997, has no homology to Applicants' CAPN11 protein of SEQ ID NO: 2 (see enclosure). Therefore, the teachings of Honbou et al cannot be used as evidence to support Applicants' assertion that the protein of SEQ ID NO: 2 is involved in male fertility.

For these reasons and those explained in the prior action, rejection of Claims 1-5 under 35 U.S.C. 101/112 because the claimed invention lacks a substantial and specific utility is maintained.

Written Description

Rejection of Claims 4 and 5 under 35 U.S.C. 112, first paragraph/written description, as described in the prior actions, is maintained.

In support of their request that said rejection be withdrawn, Applicants argue that the specification, at page 4, clearly discloses that CAPN11 is a calcium-dependent protease. This is the identical argument Applicants' presented in their response of November 13, 2006. Applicants are referred by to the Office's reply provided in the action mailed January 12, 2007. In brief, mere assertion that the protein of SEQ ID NO: 2 has homology to chicken μ m calpain, is not a disclosure of a method for identifying inhibitor for the protein of SEQ ID NO: 2.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to reject amended claims or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
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A handwritten signature in black ink, appearing to read 'Swope', with a large loop at the top and a horizontal stroke at the bottom.

SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER